

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BRENDA SMITH, Individually and
as Administratrix of the Estate of
RICKY SMITH,

Plaintiffs

vs.

SAMIR B. PANCHOLY, M.D.
FACC, FSCAI; SAMIR B.
PANCHOLY, LLC; NORTH PENN
CARDIOVASCULAR
SPECIALISTS; HAITHAM
ABUGHNIA, M.D.; and
BIOTRONIK, INC.,

Defendants

CIVIL ACTION – LAW

NO.: 3:16-CV-1264

JUDGE: MARIANI

JURY TRIAL DEMANDED

ELECTRONICALLY FILED

AMENDED COMPLAINT

1. Plaintiff, Brenda Smith, is an adult individual, residing at 3386 State Rte. 3009, Meshoppen, Susquehanna County, Pennsylvania, 18630.

2. Plaintiff, Brenda Smith, is the wife of Decedent Ricky Smith. Plaintiff Brenda Smith witnessed acts and omissions constituting negligence and the damage which occurred to Ricky Smith.

3. Ricky Smith was born on August 7, 1955. Ricky Smith was 58 years old at the time of his death on March 11, 2014.

4. Plaintiff, Brenda Smith, pursuant to Letters of Administration issued on December 8, 2015, by the Register of Wills of Susquehanna County, was appointed Administrator of the Estate of Ricky Smith (hereinafter "Ricky").

5. Defendant, Samir B. Pancholy, M.D., FACC, FSCAI, is an adult individual who is Board Certified in Internal Medicine and who holds himself out as competent to provide cardiovascular services. At the time of the occurrences, Defendant was an employee and/or agent, ostensible agent, apparent agent, partner, or had a legal relationship providing vicarious liability with Defendant Samir B. Pancholy, LLC, and/or North Penn Cardiovascular Specialists, both of which utilize a business address of 401 North State Street, Clarks Summit, Lackawanna County, Pennsylvania. Plaintiffs are asserting a professional liability action against these Defendants.

6. According to the Department of State, Commonwealth of Pennsylvania, Samir Pancholy is an LLC owned by Samir Pancholy, medical doctor, with its address listed as 401 North State Street, Clarks Summit,

Lackawanna County, Pennsylvania 18411. On information and belief, the LLC is a corporation or other legal entity organized pursuant to the laws of the Commonwealth of Pennsylvania and is engaged in the business of providing health care services to the public and maintains a place of business at 401 North State Street, Clarks Summit, Lackawanna County, Pennsylvania 18411, the same address as North Penn Cardiovascular Specialists, Lackawanna County, Pennsylvania. On information and belief, Samir B. Pancholy, MD, FACC, FSCAI was, or may have been an employee and/or agent, ostensible/apparent or otherwise, servant or partner of the LLC and/or owner thereof at the time of the occurrences alleged herein. Plaintiffs are asserting a professional liability action against this Defendant.

7. North Penn Cardiovascular Specialists, upon information and belief, is a corporation or other legal entity organized under the laws of the Commonwealth of Pennsylvania and is engaged in the business of providing health care services to the public and maintains a place of business at 401 North State Street, Clarks Summit, Lackawanna County, Pennsylvania. Upon information and belief, Defendant Samir B. Pancholy, M.D., FACC, FSCAI was or may have been an employee, and/or agent, ostensible/apparent or otherwise, servant or partner of North Penn Cardiovascular Specialists at the time of the occurrences alleged herein. Plaintiffs are asserting a professional liability claim against this Defendant.

8. Defendant, Haitham Abughnia, M.D., is an adult individual, a physician who is Board Certified in Internal Medicine and who holds himself out as competent to provide cardiovascular services. At the time of the occurrences alleged herein, Defendant was an employee and/or agent, ostensible agent, apparent agent, partner, or has another legal relationship providing vicarious liability with Defendant Samir B. Pancholy, and/or LLC, and/or North Penn Cardiovascular Specialists, which utilizes a business address of 401 North State Street, Clarks Summit, Lackawanna County, Pennsylvania. Plaintiffs are asserting a professional liability claim against this Defendant.

9. Dr. Pancholy, the LLC, and North Penn Cardiovascular Specialists will hereinafter be referred to as “Dr. Pancholy.”

10. On information and belief, Defendant Biotronik, Inc., is a legal entity, duly organized and existing under the laws of the State of Oregon with a principal place of business at 6024 Jean Road, Lake Oswego, Clackamas County, Oregon.

11. Defendant Biotronik, Inc. is found doing business on a regular and substantial basis in the County of Lackawanna, Commonwealth of Pennsylvania.

FACTS

12. The preceding paragraphs are incorporated herein by reference as though fully set forth.

13. On or about December 22, 2006, Decedent Ricky Smith had three (3) cardiac leads implanted and had insertion of an Internal Cardioverter Defibrillator (ICD) as treatment for cardiomyopathy with implantation performed by Defendant Pancholy.

14. One of the cardiac leads was a right ventricular (RV) lead brand name, Linx SD 65/16, serial number 10264272, manufactured, supplied and distributed by Defendant Biotronik and utilized by Defendant Pancholy.

15. On or about May 19, 2009, Defendant Pancholy replaced and/or exchanged the implanted device by utilizing an ICD Model No. Lumax 340 HF-T, also manufactured, supplied, and distributed by Biotronik.

16. The leads, which were never changed out, were also manufactured, supplied, and distributed by Biotronik.

17. Defendant Pancholy and Defendant Abughnia of North Penn Cardiovascular Specialists provided continuous care to Mr. Smith in connection with his cardiovascular function, the implanted device and the leads.

18. On or about February 27, 2013, an episode of VF (ventricular fibrillation) occurred according to the Biotronik home monitoring.

19. On information and belief, the “VF” detected was indication of noise in the lead suggesting the initiation of lead failure.

20. Lead failure is progressive.

21. Lead failure greatly increases the risk of inappropriate cardiac shock which may be fatal to the patient.

22. On or about March 25, 2013, Decedent received a shock from the defibrillator. He had no associated cardiac symptoms. The episode was reported to Dr. Pancholy’s office.

23. Brenda Smith, aware of the shock her husband received, took Ricky Smith to Dr. Pancholy’s office where the device was interrogated. Interrogation is a term for scanning or reading the device.

24. The interrogation of the device on or about March 26, 2013, upon information and belief, revealed the shock documented on March 25, 2013 at approximately 3:38 p.m.

25. On information and belief, on or about March 26, 2013, Decedent was seen by Dr. Pancholy.

26. Dr. Pancholy did not address the shock of March 25, 2013.

27. Dr. Pancholy examined Ricky Smith on or about May 2, 2013, made no program changes and anticipated routine follow up in three (3) months.

28. In July, August, and September 2013, at least 8 more episodes of “VF” and at least “7 spontaneous episodes” were detected by Biotronik’s home monitoring which were all reported to Dr. Pancholy’s office.

29. The associated “episode details” for the events hereinbefore recited are missing from the medical records.

30. It is believed and therefore averred that those missing “episode details” represent spoliation and justify an adverse inference against Defendants.

31. The reporting as set forth above demonstrates that Defendants knew or had reason to know of information which would have placed them on notice of Ricky Smith’s precarious situation and risk of a shock which could cause cardiac arrhythmia, fibrillation and death.

32. Defendants, as a consequence of what they knew or had reason to know, were placed on a duty of inquiry with respect to the condition of the leads, the operation of the device, and the risk of shocking, arrhythmia, and death to Mr. Ricky Smith.

33. Upon information and belief, reasonable inquiry would have revealed that the alleged episodes of “VF” in July, August and September of 2013, were not “VF” but noise in the leads indicating lead failure which increased the risk of unnecessary shocks, arrhythmia, and death.

34. The events described above, upon information and belief, were indicative of lead failure and placed Defendants on notice to utilize reasonable diligence and duty of inquiry to appreciate that the leads were failing or needed to be checked or replaced because of the risk of harm to Ricky Smith, which they nevertheless did not do in reckless disregard of the consequences to Ricky Smith.

35. A damaged lead creates noise which a device may interpret as “VF” and thus the device will inappropriately shock the patient, contributing to arrhythmia and death.

36. The failure of Defendants to perform a non-negligent and diligent professional inquiry, and replace the leads, culminated in the leads causing the device to shock the patient Ricky Smith thus causing arrhythmia and death.

37. Upon information and belief, on or about September 30, 2013, Defendant Pancholy interrogated the device revealing electrograms dated August 31, 2013, that indicate clear and significant noise in the “RV” sensing channel. This was or should have been indication of lead failure that warranted immediate attention and lead replacement which did not occur.

38. On or about September 30, 2013, Defendant Pancholy recorded “normal function without shock.”

39. On or about September 30, 2013, Defendant Pancholy recorded “Noise seen on ICD check. Program changed to prevent inappropriate shock. Will monitor for lead function.”

40. Dr. Pancholy did not record in his records the program changes he made on September 30, 2013.

41. Dr. Pancholy changed the “RV” lead sensing threshold to decrease the sensitivity of the device further.

42. Despite his knowledge of the foregoing VF episodes and of the noise in the RV sensing channel, which were indicative of lead failure, Dr. Pancholy permitted a damaged and failing lead to remain in the patient, which was a highly reckless and dangerous act culminating in the death of his patient.

43. The type of noise seen on the “RV” lead of August/September 2013 indicated a serious problem with the lead which constituted either a partially fractured conductor, a break in the lead insulation, or some other serious condition that needed to be addressed.

44. The condition of the lead and/or conductor and/or insulation warranted prompt replacement of the “RV” lead which Defendant Pancholy did not perform.

45. The program changes made by Defendant Pancholy on September 30, 2013, were inadequate to address the lead failure.

46. By reducing the sensitivity of the device, Defendant Pancholy did not address the problem. This failure increased the risk of inappropriate shocks taking place leading to arrhythmia and death of his patient.

47. Dr. Pancholy was obligated emergently to replace the failed “RV” lead, which he never did.

48. On or about November 1, 2013, upon information and belief, Biotronik’s cardiac home monitoring detected another episode of “VF” that represented continuing problems with the noise on the lead, indicating a defective and/or broken lead conductor or a break in the lead insulation or some other serious condition that needed to be addressed.

49. The associated “episode details” for November 1, 2013, are missing from the records.

50. It is believed and therefore averred that those missing events represent spoliation and justify an adverse inference against Defendants.

51. On or about January 24, 2014, Decedent Ricky Smith was seen by Defendant Abughnia who charted, “excellent symptoms improvement” and “continue present treatment.”

52. Dr. Abughnia either did not review the records which was incompetent, negligent and reckless, or reviewed them and nevertheless arrived at incompetent, negligent and reckless conclusions.

53. On or about January 24, 2014, Defendant Pancholy charted, “Noise on lead adjusted criteria.”

54. The final office visit by Decedent Ricky Smith to Defendant Pancholy took place on or about February 28, 2014.

55. On March 10, 2014, there was a documented episode of “VF” which represented continuing lead noise indicating a compromised and/or failed lead and/or conductor and/or insulation, or some other serious condition that needed to be addressed.

56. Dr. Pancholy’s orders at Regional Hospital of Scranton on March 11, 2014, indicated plans for ICD generator change with possible lead replacement that day.

57. The operative consent signed by Ricky Smith on March 11, 2014, was only for ICD generator change and not lead replacement.

58. Defendant Pancholy’s operative report stated on March 11, 2014, that he was performing surgery for “internal cardioverter defibrillator generator end-of-life” and “right ventricular shocking lead noise.”

59. Dr. Pancholy was aware of the lead noise and nevertheless exposed his patient to a recklessly high risk of shocking, arrhythmia, and death by not replacing the failed lead.

60. Defendant Pancholy claimed normal “RV” lead function during surgery and charted that he tested and found no evidence of lead noise during surgery.

61. On March 11, 2014, Dr. Pancholy only replaced the ICD generator and opted not to change the “RV” lead or any other lead. This was a reckless act in view of the history of lead noise.

62. The ICD generator implanted by Defendant Pancholy on or about March 11, 2014, was a Biotronik, Model Lumax 740 HF-T, serial number 60701903.

63. A Biotronik representative, on information and belief, was present during the surgery. Biotronik, through its representative, undertook to provide technical information, opinion and advice to Dr. Pancholy with respect to the viability and safety of the Biotronik product and its collateral components, and in particular, the leads. Biotronik sells, supplies and delivers not merely tangible objects but also advice, monitoring, purportedly “expert” field representation and technical assistance to physicians and ultimately patients.

64. Defendant Biotronik, through its representative, knew, or had reason to know, of issues and concerns with respect to the lead at the time and place aforesaid and disregarded same, to the detriment of Decedent.

65. Replacing a generator may actually cause a poorly functioning or failing lead to become worse thereby increasing the risk of a patient to receive an inappropriate shock.

66. Defendant Pancholy did not perform defibrillation testing of the new generator in surgery on March 11, 2014.

67. This represents a violation of the standard of care in connection with generator replacement, especially in conjunction with indication of lead failure.

68. Defendant Pancholy's action was reckless, wanton and negligent, and subjected his patient to a known high risk of unnecessary shock, arrhythmia and death.

69. Brenda Smith had been told there was noise on the lead and that it might be changed in surgery, in which case Ricky Smith would be kept overnight. Brenda Smith was fully expecting an overnight stay, and made arrangements accordingly. Brenda Smith was surprised when she was told that the doctor found no noise and that Ricky was "good to go." She specifically asked whether the doctors were sure. Although Brenda Smith chose to accept what the doctors told her, nevertheless she questioned their actions in her own mind and worried about the propriety of not changing the leads.

70. At approximately 4:15 p.m., after his surgery on March 11, 2014, Ricky Smith was discharged to his home after which he received several shocks from the newly implanted ICD.

71. There were multiple shocks that day associated with left arm movement, but none of which were associated with cardiac symptoms.

72. Brenda Smith called Regional Hospital after the first shock.

73. A shock occurred at or about 6:03 p.m., and caused Decedent to collapse at his home.

74. Brenda Smith called the EMS and initiated CPR.

75. At 6:20 p.m., EMS discovered Decedent in pulseless electrical activity (PEA), according to the cardiac monitoring.

76. EMS continued to do CPR and transported Decedent by ambulance to Tyler Memorial Hospital.

77. In spite of efforts to save the patient, he was pronounced dead at 7:05 p.m. March 11, 2014, at Tyler Memorial Hospital.

78. Brenda Smith witnessed the shocks and the occurrence of negligence to her husband and the consequence of that negligence including the collapse, suffering, struggles, and death ultimately of her husband.

79. As a result of what Brenda Smith experienced as stated herein, she has experienced and continues to experience sleeplessness. She has bad dreams, upset,

and continues to have nightmares. After Ricky Smith died, Brenda began drinking and gambling, and experienced stress that she would get into trouble because of her behavior. Brenda Smith was ashamed of herself and felt that she was not acting consistently with her own background and lifestyle.

80. Interrogation data for March 11, 2014, reveals a clinical rhythm of “VF”, under-sensing of the “RV” lead, noise on the lead, shocks of 40 joules delivered by the device that failed to terminate the “VF” or restore normal heart rhythm, and a very high shock impedance (>150 ohms).

81. Interrogation data reveals a device and/or lead malfunction and failure of the high voltage “RV” lead circuit.

82. Cardiac data demonstrates ICD device and/or lead malfunction that caused Decedent’s inappropriate, unnecessary cardiac shocks triggered by noise on the “RV” lead.

83. The interrogation data for March 11, 2014, reveals that at approximately 5:50 p.m., Ricky’s ICD device delivered a 40 joules shock with an impedance <25 .

84. The low impedance indicates a short in the lead indicative of a lead insulation problem.

85. The above ICD shock resulted in further lead damage to an already failing lead.

86. At approximately 6:03 p.m., there is lead noise evident while Ricky Smith was in a normal sinus rhythm.

87. The lead noise at 6:03 p.m. precipitated another 40 joules shock that resulted in ventricular fibrillation which caused the death of Ricky Smith.

88. The cardiac data further demonstrates that the device did not effectively treat the ventricular fibrillation due to failure of high voltage “RV” lead circuit.

89. The inappropriate and unnecessary shocks precipitated a cardiac arrhythmia that resulted in Decedent’s collapse, struggling, pain and suffering and subsequent death, all of which was witnessed by his wife, Brenda Smith.

COUNT I

Defendant Samir B. Pancholy, M.D., FACC, FSCAI

90. The preceding paragraphs are incorporated herein by reference as though fully set forth.

91. Defendant Pancholy held himself out to be a health care provider who possessed skill and knowledge in his specialty and held himself out to the public and to Decedent as though fully qualified.

92. Defendant Pancholy failed to provide reasonable health care, was negligent, caused injury, and/or increased the risk of harm as follows:

92.1 By failing adequately to evaluate and respond to multiple indications of RV lead failure, including; but not limited to the following:

92.1.1 The shock the patient received on 3/25/13, which was triggered by lead noise, and was never addressed clinically;

92.1.2 Multiple episodes of noise documented on remote Home Monitoring in 2013, including electrograms dated 8/31/13 that showed clear lead noise consistent with lead failure; and

92.1.3 Noise seen on the RV sensing channel.

92.2 By failing, in spite of accumulating evidence for lead failure, to take appropriate action, to monitor the situation or to replace the leads;

92.3 By failing to properly examine and replace leads before the generator change performed on the day of death;

92.4 By believing that the failure to reproduce the noise at the time of generator change was a reason not to replace the leads;

92.5 By failing to react to the indication of lead malfunction prior to generator change, and believing that additional information was required;

92.6 By failing to perform a thorough evaluation of lead function at the time of the generator change;

92.7 By failing in surgery to induce VF and testing the leads' ability to detect and terminate VF;

92.8 By failing or refusing to properly check out the leads, the conductors, the generator, and to assure that all were working properly, not malfunctioning, and not in a position to provide a shock to the patient when the shock was not necessary;

92.9 By failing or refusing to take action to test, document and monitor the equipment as aforesaid so as to assure that it would not misinterpret data as an arrhythmia requiring shock;

92.10 By failing and refusing to educate himself to the operation, function, testing, and understanding of the equipment as aforesaid and how it should operate so as not to shock and therefore kill the patient;

92.11 By inappropriately relying upon the examination conducted of the device and leads on the day of Decedent's death rather than considering the constellation of information at his disposal;

92.12 In the alternative, by relying upon statements or conduct of the Biotronik representative;

92.13 On information and belief, by failing or refusing to inform himself as to whether the generator, leads or other components were functioning properly, or whether one or more of the components should have been removed and replaced;

92.14 By increasing the shock impedance and ignoring the malfunction for a lead that needed to be changed;

92.15 By not responding to the temporal association of shocks with generator change on the same day, the date of death, as chronic lead malfunction may manifest itself surely after generator change and not understanding or recognizing same;

92.16 By not understanding or properly responding to the absence of premonitory symptoms of arrhythmia prior to the shocks on the day of death;

92.17 By not appreciating or understanding that replacement of the generator would enhance the propensity of defective or failing leads to shock the patient, causing arrhythmia and death.

92.18 By failing to appreciate or respond to the fact that one or more of the inappropriate shocks that Decedent received could

precipitate a cardiac arrhythmia leading to the patient's collapse and ultimately to his death.

93. As a direct and factual result of the conduct set forth above, Decedent suffered pain and suffering, fear of death, and death.

94. Dr. Pancholy permitted to remain in the patient damaged leads and/or damaged lead conductors and/or insulation which was reckless and wanton and represented subjecting his patient to a known risk which caused death.

95. The unnecessary shocking as a result of the damaged device and/or leads caused considerable pain and discomfort to Decedent, and on many occasions was witnessed by his wife who suffered emotional distress as a result of what she witnessed.

96. As a direct and factual result of Defendant's failures, Ricky Smith suffered injuries and died and Brenda Smith suffered emotional distress.

WHEREFORE, Plaintiffs demand judgment against Defendant for an amount in excess of the limits of arbitration, excluding interests and costs.

COUNT II

Defendant Haitham Abughnia, M.D.

97. The preceding paragraphs are incorporated herein by reference as though set forth fully.

98. On or about January 24, 2014, Decedent Ricky Smith was seen by Defendant Abughnia who charted “excellent symptoms and improvement” and “continue present treatment.”

99. Dr. Abughnia either did not review the records which was incompetent, negligent and reckless or reviewed them and nevertheless arrived at incompetent, negligent and reckless conclusions.

100. Defendant Abughnia failed to provide reasonable health care, was negligent, caused injury, and/or increased the risk of harm as follows:

100.1 By failing adequately to evaluate and respond to multiple indications of RV lead failure, including; but not limited to the following:

100.1.1 Reviewing the medical chart and the indications as aforesaid and incorporated herein by reference from Count I;

100.1.2 By failing or refusing to examine the chart and treat the patient for multiple episodes of noise documented, including electrograms that showed clear lead noise typical of lead failure;

100.1.3 By failing or refusing to examine the patient chart and appreciate that the patient was at high

risk for inappropriate shocking that could lead to the patient's pain, suffering and death;

100.1.4 By failing or refusing to consult with Dr. Pancholy;

100.1.5 By failing or refusing to exercise his judgment as a professional in not only examining the patient but also looking at the records and the materials available to him to see if the patient was at high risk for inappropriate shocking.

100.2 By failing, in spite of accumulating evidence for lead failure, to take appropriate action, to monitor the situation or to replace the leads.

101. As a direct and factual result of the conduct set forth above, Decedent suffered pain and suffering, fear of death, and death.

102. As a direct and factual result of Defendant's failures, Ricky Smith suffered injuries and died.

WHEREFORE, Plaintiffs demand judgment against Defendant for an amount in excess of the limits of arbitration, excluding interests and costs.

COUNT III

Samir B. Pancholy, LLC

103. The preceding paragraphs are incorporated herein by reference as though fully set forth.

104. The Pancholy LLC, upon information and belief, is a legal entity created by Dr. Pancholy to insulate himself from liability.

105. The LLC is responsible for the actions or inactions of its agents, servants and/or employees, ostensible or otherwise who provided medical care to Decedent Ricky Smith.

106. Upon information and belief, Defendant Samir B. Pancholy, M.D., FACC, FSCAI, was an employee, agent, servant and/or officer, ostensible or otherwise, of Samir B. Pancholy, LLC.

107. At all relevant times, Defendant Pancholy was acting within the scope of his employment as an employee, agent, servant, and/or officer, ostensible or otherwise with Samir B. Pancholy, LLC.

108. As a direct and factual result of the failures and conduct of Defendant's agent, Ricky Smith suffered injuries and died and Brenda Smith suffered emotional distress.

WHEREFORE, Plaintiffs demand judgment against Defendant for an amount in excess of the limits of arbitration, excluding interests and costs.

COUNT IV

North Penn Cardiovascular Specialists

109. The preceding paragraphs are incorporated herein by reference as though fully set forth.

110. North Penn Cardiovascular Specialists is responsible for the actions or inactions of its agents, servants and/or employees, ostensible or otherwise who provided medical care to Decedent Ricky Smith.

111. Upon information and belief, Defendant Samir B. Pancholy, M.D., FACC, FSCAI, was an employee, agent, servant and/or officer, ostensible or otherwise, of North Penn Cardiovascular Specialists.

112. At all relevant times, Defendant Pancholy was acting within the scope of his employment as an employee, agent, servant, and/or officer, ostensible or otherwise with North Penn Cardiovascular Specialists.

113. Upon information and belief, Defendant Haitham Abughnia, M.D., was an employee, agent, servant and/or officer, ostensible or otherwise, of North Penn Cardiovascular Specialists.

114. At all relevant times, Defendant Haitham Abughnia, M.D., was acting within the scope of his employment as an employee, agent, servant, and/or officer, ostensible or otherwise with North Penn Cardiovascular Specialists.

115. As a direct and factual result of the failures and conduct of Defendant's agents, Ricky Smith suffered injuries and died and as a result of the conduct of Defendant Pancholy, Brenda Smith suffered emotional distress.

WHEREFORE, Plaintiffs demand judgment against Defendant for an amount in excess of the limits of arbitration, excluding interests and costs.

COUNT V
Biotronik, Inc.

116. The preceding paragraphs are incorporated by reference as though set forth fully herein.

117. Defendant Biotronik manufactured, distributed and supplied the device, including all of its appurtenances, conductors, wiring, batteries and, in addition, provided for electronic surveillance, monitoring, relay of data to physicians and the manufacturer's own electronic storage and electronic storage available to the manufacturer, distributor or supplier.

118. Defendant Biotronik manufactured all the components, and distributed, supplied and/or branded same.

119. The product is sold, supplied, manufactured and distributed in a unitary fashion, including but not limited to the product, leads, conductors,

generators, batteries, monitoring functions and advice consultation to physicians and healthcare providers.

120. Biotronik explicitly represents on its website that it is one of the world's leading manufacturers of cardio- and endovascular medical devices represented in over 100 countries. "Several million patients have received BIOTRONIK implants designed to save lives and improve quality of life." Biotronik states that its mission is to develop and manufacture products "of the highest quality that save patients' lives and improve their quality of life." The website further states: "We deliver innovative cardio-and endovascular solutions that address the needs of patients and physicians. From the very beginning, we have had a passion for developing and manufacturing the most precise and highest quality products on the market."

121. Biotronik further represents, "From design to manufacturing, we engineer devices that surpass industry safety and reliability standards. Our therapies are clinically proven, prevent sudden cardiac arrest, and benefit patients, for example in reducing hospitalization." Biotronik represents that it offers customers "**excellent SERVICE.**" Biotronik represents that it educates physicians how to implant devices, supporting them in person during complicated implantations. "We offer our customers unmatched educational, logistical and

technical support.” These statements and other advertising representations and holding out by Biotronik are distributed to the public and directly to physicians.

122. Physicians, end users and patients rely upon these representations, in this case to their detriment. The representations are material.

123. The device, components and the monitoring and advice functions were utilized by Defendant healthcare providers as aforesaid in connection with the care and treatment of Plaintiffs’ Decedent.

124. It is understood and expected by the patient and healthcare provider that they will be properly advised with respect to the product, its components, the longevity of the components, when leads and conductors or other parts should be replaced.

125. On information and belief, the healthcare provider and patient relied upon Biotronik through its representative to properly advise healthcare providers with respect to the meaning of “noise” and other matters of importance as aforesaid.

126. On information and belief, on one or more occasions the manufacturer had a representative who was their agent, servant or employee present when Ricky Smith was treated and/or consulted with the treating physicians.

127. Those agents, servants or employees of Biotronik were negligent, gave improper advice, did not give proper information or warnings, and did not

consult with the patient's physicians in a competent, non-negligent fashion, thus causing pain, suffering and death to Ricky Smith.

128. It is further alleged, in particular, that on March 11, 2014, Biotronik, through its technical representative, did not properly and competently inform, warn or advise the physicians caring for Decedent in connection with the longevity of the device, the leads, the conductors and the other components, who relied upon the technical expertise of said representative with regard to the device and the leads and whether the leads required replacement. Such lack of proper information and/or negligent advice resulted in the physicians not replacing the leads and/or conductors of this particular device implanted in Ricky Smith, in spite of clear indications that they were defective, failing or otherwise in need of replacement, thus causing the patient to be inappropriately shocked when he was not suffering an arrhythmia.

129. Defendant Biotronik is vicariously liable for the negligent statements, advice and/or omissions of its representative(s).

130. In addition, on information and belief, Biotronik does not have or has not saved, either on its hard drive, the cloud or anywhere else, all the data which the company represented that it would receive for the utility of patient and health care providers, thus impairing Plaintiff's discovery in presenting her case. Such

failure to properly receive, save and store data is spoliation, and warrants an adverse inference or other sanction.

131. Biotronik, through its representative(s), failed in its obligation undertaken to advise healthcare providers and consumers in connection with the product as aforesaid, as to when the leads and/or conductor or other components should be replaced, the significance of information such as noise, and failed and refused properly to interrogate the equipment, save that data, and impart crucial information to the healthcare provider and the patient in a way that would have prevented the device from inappropriately shocking the patient, causing arrhythmia and death.

132. As a direct and factual result of Defendant's failures, Ricky Smith suffered injury and died.

WHEREFORE, Plaintiffs demand judgment against Defendant for an amount in excess of the limits of arbitration, excluding interests and costs.

COUNT VI
Punitive damages
DEFENDANT PANCHOLY

133. The preceding paragraphs are incorporated by reference as though set forth fully herein.

134. The conduct of Defendant Pancholy was either reckless or sufficiently in disregard of the interests of Decedent and represented willful and wanton conduct or reckless indifference to the rights of Decedent.

135. The character of the conduct or failure to act was such that the nature and extent of the harm to Ricky Smith was catastrophic.

136. The conduct or omissions consisted of subjective awareness of the risk to Decedent which Defendant consciously chose to disregard in terms of the risks and awareness of those risks.

137. Defendant Pancholy's actions and omissions as set forth hereinbefore constitute willful and wanton conduct or reckless indifference as aforesaid, and more particularly as follows:

137.1 Defendant Pancholy was aware and had reason to know of Decedent's risk factors and the need to have reliably working equipment in connection with his potential arrhythmia;

137.2 Defendant Pancholy had explicit notice of the failing or failure of said equipment as aforesaid and he nevertheless chose to disregard same, enhancing serious risk of harm to Decedent which in fact occurred;

137.3 Defendant Pancholy knew the meaning and significance of lead noise and how the product would react to same;

137.4 Defendant Pancholy, by knowing explicitly the risk to his patient, the status of the product and the risk of not changing out the leads and/or conductor and/or insulation while replacing the generator, represented a disregard consciously of the risks to Decedent;

137.5 Defendant Pancholy had multiple opportunities to appreciate and learn that the lead and/or conductor and/or insulation was failing or had failed and nevertheless failed or refused to respond in order to prevent Decedent from suffering unnecessary shocks and ultimately death;

137.6 Decedent was shocked, and Defendant Pancholy either knew of that or had every reason to know about it but either consciously disregarded same or did not investigate the information readily at his disposal; and

137.7 Defendant Pancholy knew that his conduct or omissions would create a life threatening risk to Ricky Smith, which actually occurred.

138. As a direct and factual cause of Defendant's conduct and omissions, Plaintiffs have suffered the damages set forth herein and are entitled to punitive damages as may be permitted by law.

WHEREFORE, Plaintiffs demand judgment be entered against Defendant Pancholy for an amount in excess of the limits of arbitration, exclusive of interest or costs, including punitive damages.

COUNT VII

Wrongful Death

139. The preceding paragraphs are incorporated by reference as though set forth fully herein.

140. Due to the conduct of Defendants, as aforesaid, Decedent died and has left individuals entitled to recover for his death.

141. Plaintiffs bring this action under and by virtue of 42 Pa. C.S.A. §8301 and Pa. R.C.P. 2202(a) on her own behalf and on behalf of those entitled to recover damages for the wrongful death of Decedent. Plaintiffs, by reason of the death of Decedent, are entitled to recover in addition to other damages, amounts for reasonable hospital and medical expenses, funeral expenses, financial losses, including loss of right to future maintenance and support and other expenses of administration of the estate.

142. Decedent's statutory survivors consist of Decedent's wife, Brenda Smith, who resides at 3386 State Rte. 3009, Meshoppen, Pennsylvania, 18630.

143. Decedent's statutory survivor has suffered the loss of Decedent's services, companionship, society, comfort, guidance, solace, and protection, and other damages as are recoverable under the Wrongful Death Act of Pennsylvania.

144. Decedent did not bring an action for personal injuries during his lifetime.

145. As a direct and factual cause of Defendants' conduct and omissions, Plaintiffs have suffered the damages set forth herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for an amount in excess of the limits of arbitration, excluding interests and costs.

COUNT VIII
Survival Action
PLAINTIFFS v. ALL DEFENDANTS

146. The preceding paragraphs are incorporated by reference as though set forth fully herein.

147. Plaintiffs bring this action on behalf of the Estate of Ricky Smith under and by virtue of the laws of the Commonwealth of Pennsylvania, 42 Pa. C. S. Section 8302 and 20 Pa. C. S. Section 3373.

148. Plaintiffs claim, on behalf of said estate, damages suffered by reason of the death of Ricky Smith, including the following:

- a. Decedent's mental and physical pain, suffering and inconvenience prior to his death;
- b. Decedent's future earnings and loss of future earning capacity;
- c. Decedent's other financial losses suffered as a result of his death;
- d. Decedent's loss of enjoyment of life prior to death;
- e. Such other damages as are recoverable in a survival action; and
- f. Punitive damages against Defendant Pancholy.

149. As a direct and factual cause of Defendants' conduct and omissions, Plaintiffs have suffered the damages set forth herein and are entitled to punitive damages as may be permitted by law.

WHEREFORE, Plaintiffs demand judgment against Defendants for an amount in excess of the limits of arbitration, including interests and costs.

COUNT IX
Negligent Infliction of Emotional Distress
v. Defendant Pancholy

150. The preceding paragraphs are incorporated by reference as though set forth fully herein.

151. Plaintiff Brenda Smith observed and experienced the lack of due care provided, including the consequence of the acts and omissions which resulted in the death of her husband, Ricky Smith.

152. Plaintiff Brenda Smith contemporaneously observed, experienced and/or perceived by sight and sound the pain and suffering and impact on the health of her husband, the inappropriate shocking, his pain in having received the inappropriate shocks, and his death.

153. Plaintiff Brenda Smith observed, heard, experienced and was aware of the negligent failure by Defendant Pancholy to appropriately treat her husband's condition and his conduct or omissions in providing medical care to her husband and at a minimum questioned/was concerned with respect to same.

154. As a result of the conduct and omissions of Defendant Pancholy, Plaintiff Brenda Smith experienced and/or observed the discreet and identifiable traumatic event, the shocking and death of her husband, which resulted in Plaintiff Brenda Smith suffering and continuing to suffer serious permanent emotional distress and mental anguish resulting in physical manifestations of symptoms such as sleeplessness, nightmares and drinking.

155. It was and should have been reasonably foreseeable to Defendant Pancholy that his conduct and omissions would result in Plaintiff Brenda Smith experiencing severe emotional distress.

156. As a factual cause of Plaintiff Brenda Smith's contemporaneously experiencing and/or perceiving by sight and sound the actions and omissions of Defendant, the inappropriate shocking and death of her husband, Plaintiff Brenda Smith suffers and continues to suffer serious and permanent emotional distress and mental anguish, including both physical and emotional manifestation of damages as aforesaid.

157. Plaintiff Brenda Smith specifically expressed surprise and doubt concerning the treatment rendered to her husband in connection with the failure to replace the leads.

158. Brenda Smith questioned whether the care provided to Ricky Smith was proper. After being told there was "noise", Brenda Smith believed the leads would be changed or that care would be provided to assure that the leads were working properly. Brenda Smith questioned and was concerned about whether it was appropriate not to change the leads. She relied upon the acts, omissions and statements of Defendant.

159. As a direct and factual result of Defendant's conduct, Plaintiff Brenda Smith suffered emotional distress and its manifestations as aforesaid.

WHEREFORE, Plaintiff demands judgment against Defendant Pancholy in an amount in excess of the limits of arbitration, exclusive of interest and costs.

RIEDERS, TRAVIS, HUMPHREY,
WATERS & DOHRMANN

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CERTIFICATE OF SERVICE

AND NOW, comes Clifford A. Rieders, Esquire and C. Scott Waters, Esquire, attorneys for Plaintiffs and certifies that the foregoing AMENDED COMPLAINT has this 15th day of July 2016, filed electronically and served pursuant to the Court's ECF system upon the following:

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